3069 POSTER

Granulocyte Colony-stimulating Factors (G-CSF) Use in Clinical Practice: PoloNord Group Registry-Based Cohort Study

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Background: G-CSFs are widely used to reduce myelotoxicity of chemotherapy (Th) and to allow its regular administration. National and International Guidelines (GU) recommend their use. The aim of the study is to evaluate G-CSF, Pegfilgrastim (PEG) and Filgrastim/Lenograstim (FL), *patterns of use* in clinical practice (CP), comparing their *adherence* to AIOM (Medical Oncology Italian Association) GU, *effectiveness* and *tolerability*.
Materials and Methods: Data from 622 consecutive patients (pts), receiving G-CSF for the first time during a line of Th, were enrolled from 09/2008 to 11/2010, in 10 Lombardy Italian cancer centers. Data recorded by 2882 follow-up (FU), corrisponding to Th cycles: age, neoplastic disease and stage, Th regimens, febrile neutropenia risk (high or low) according to pts risk factors, blood counts, kind of G-CSF and patterns of use, febrile neutropenia (FN), G3−4 neutropenia, hospitalization due to infections (HDI), dose reduction (DR), Th delay (ThD) and bone pain.
Results: *Patterns of use*: primary prophylaxis (722 FU) PEG 43% vs FL 57%; secondary prophylaxis (1340 FU) PEG 14% vs FL 86%; therapeutic use (356 FU) FL only. Mainly G-CSF supported neoplastic diseases (622 pts): breast cancer (B) 229 (37%), lung cancer (L) 102 (16%) and lymphomas (LY) 71 (11%), but with different use modality: B $\rightarrow$ main use in adjuvant therapy (141; 62%), to guarantee dose intensity in pts at low risk of FN (137; 60%); L/LY (102/71 pts) $\rightarrow$ main use in advanced disease (L90%, LY100%), to support pts at high risk of FN (L72%, LY69%).
Adherence to GU: Primary prophylaxis: PEG 75% (64/85pts) vs FL 55% (53/97pts) ($p = 0.006$); Secondary prophylaxis: PEG 16% (10/64pts) vs FL 25%(78/313pts), but PEG 59% (38/64pts) vs FL 63% (197/313pts) including pts at high risk of FN; Timing start G-CSF: PEG 501/504 FU, 99% vs FL 972/1558 FU, 62% ($p < 0.00001$).
Effectiveness (PEG 504, FL 1558 FU): FN rate: PEG 8 (1.6%) vs FL 11 (0.7%) (p:NS); G3−4 neutropenia rate: PEG 30 (6%) vs FL 110 (7%) (p:NS); HDI: PEG 5 (1.0%) vs FL 4 (0.25%) (p:NS); DR: PEG 8 (1.6%) vs FL 64 (4.1%) (p:NS); ThD: PEG 13 (2.6%) vs FL 77 (5%) (p:NS).
Bone pain: PEG 37/504 (7.3%) vs FL 109/1914 (5.7%) (p:NS).
Conclusions: Results suggest the high G-CSFs effectiveness and tolerability in CP, where their use is extended beyond GU recommendations to support pts at high risk of FN and to guarantee dose intensity. The use of PEG as primary prophylaxis and timing start fits to GU more than FL, but no significant difference was found in terms of effectiveness and tolerability.

3070 POSTER

Supportive Care: What Works for Teenagers and Young Adults?

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Background: Teenagers and Young Adults (TYAs) are often referred to as 'the lost tribe'. Due to their life stage they are vulnerable to external pressures and influences, both as young people and as cancer patients. They are neither children not adults and require very different services and interventions to help them negotiate these very age specific difficulties when they are going through the cancer trajectory.
Methods: On the Young Oncology Unit at The Christie in Manchester an age appropriate psycho-social service, both on the ward and in the community, has been developed over recent years. The ward service is holistic in its approach and involves a number of professionals including youth workers, complementary therapists, music therapists, art therapists and work shop facilitators. Externally a number of different initiatives have been developed including social support groups, residential activity, service user groups, survivors groups and programmes and support services for family members and carers of TYA patients.
Results: The purpose of these services is to support young people and their families at a very difficult time. The services focus on TYAs as individuals and young people rather than as cancer patients. The approach strives to maintain young people as they were before being diagnosed and focus' on peer interaction and engagement, age appropriate activities that reinforce confidence building and self esteem and enabling TYA patients to continue to function as a young person.
Conclusions: Services continue to grow and advance and the model that has been used can be considered to be successful in that it engages many young people, both in the hospital environment and in the community.

3071 POSTER

Risk of Anaemia With Targeted Therapies − a Meta-analysis of Randomized Trials in Solid Tumours

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Background: Cancer patients suffer frequently of anaemia. Usually anaemia is both treatment- and disease- related. The risk of anaemia associated with targeted therapies is still unexplored. We did a meta-analysis to determine the incidence and the relative risk (RR) of anaemia associated with the use of biological agents.
Material and Methods: We analyzed all published randomized controlled (phase II-III) trials comparing targeted agents (alone or in combination with chemotherapy) with standard therapies alone in solid tumours. RevMan v 5.1 (Cochrane IMS) has been used for statistical analysis.
Results: A total of 46 studies were retrieved for this meta-analysis. Overall the incidence of all grade anaemia is 32% for grade [G] 1−2 and 6% for G3−4. The RRs of G1−2 anemia are in particular 1.11 ($p = 0.03$), 1.12 ($p = 0.002$) and 1.13 ($p = 0.09$) respectively for all trials pooled together, biologic agents alone and studies including targeted therapies in combination with chemotherapy agents. The risk is higher for erlotinib (RR 1.33), gefitinib (RR 2.88), sunitinib (RR 1.09), trastuzumab (RR 1.23) and mTOR inhibitors (RR 1.13) and lower for bevacizumab (RR 0.73). The analysis was also stratified for the underlying malignancy and only breast cancer trials were associated with an increased risk (RR 1.11; $p = 0.04$).
Conclusion: Anaemia with targeted therapies is a common event reported in clinical trials, in particular when these agents are prescribed as monotherapy. The treatment is supportive only because no treatment is actually approved. In the future the extension of label of erythropoietic stimulating agents with this indication could be considered.

3072 POSTER

Impact of Adherence to Antiemetic Regimens on Outcome of Nausea and Vomiting Control Among Asian Breast Cancer Patients Receiving Anthracycline-based Chemotherapy

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Background: Non-adherence to oral anticancer agents has been identified as a prevalent behavior amongst breast cancer patients. However, the prevalence of non-adherence to outpatient antiemetic regimens that are prescribed for delayed emesis prevention in breast cancer patients is limited in the literature. Hence, this study was conducted to evaluate the impact of adherence to delayed antiemetic regimens on chemotherapy induced nausea and vomiting (CINV) control in breast cancer patients, and to identify patient characteristics that may be associated with non-adherence to antiemetic regimens.
Methods: This was a prospective, observational study conducted at the largest ambulatory cancer center in Singapore from December 2006 to January 2011. All breast cancer patients receiving anthracycline-based chemotherapy and standardized outpatient antiemetic regimens were recruited. On the day of chemotherapy, patients were given a standardized 5-day diary to document their emesis events and their demographics obtained via interview. Pearson Chi-square test and multiple logistic regression were performed to analyze the impact of adherence on CINV control.
Results: A total of 361 eligible patients were included in the final analysis (mean = 50.0±8.9 years). Majority of the patients were Chinese (80.1%) and diagnosed with Stage 2 and above breast cancer (88.1%). Almost half of the patients (42.1%) were non-adherent to their prescribed delayed antiemetics regimens, with dexamethasone usage being the least adhered to (non-adherence: 37.4%). After adjusting for potential confounders (ethnicity, education level and stage of disease), patients who were adherent to antiemetics were more likely to achieve complete CINV control (defined as no emetic episodes, no nausea, and no rescue therapy required) than patients who were non-adherent (NNT=9.6; Adjusted OR=1.74, 95% CI: 1.01–3.01). In addition, young women aged between 21−40 years old, pursued higher education, and diagnosed with Stage 1 breast cancer were associated with non-adherence to antiemetics ($p < 0.05$).

Conclusion: This is the largest study to date to evaluate the prevalence of non-adherence to delayed antiemetics among breast cancer patients. Our findings indicate that a substantial amount of Asian breast cancer patients (42.1%) were not adherent to their antiemetic regimens, which may have resulted into poor control of CINV.

3073 POSTER

Randomised Phase III Clinical Trial of a Combined Treatment With Carnitine + Celecoxib +/- Megestrol Acetate for Patients With Cancer-related Anorexia/cachexia Syndrome

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Background: Cachexia accompanies the end stage of several chronic diseases, in particular, cancer, and therefore this condition is defined as "cancer-related anorexia/cachexia syndrome" (CACS): it is a multifactorial syndrome characterized by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment.
Purpose: A phase III, randomized study was carried out to compare a two-drug combination carnitine + celecoxib +/− megestrol acetate for the treatment of cancer-related anorexia/cachexia syndrome (CACS): the primary endpoints were increase of lean body mass (LBM), decrease of resting energy expenditure (REE), decrease of fatigue and improvement of total daily physical activity. Secondary endpoints were: improvement of appetite, quality of life (by the EORTC QLQ-C30), increase of physical performance tested by grip strength and six minute walk test, decrease of ECOG PS and Glasgow Prognostic Score (GPS) and decrease of proinflammatory cytokines.
Patients and Methods: Eligible patients were randomly assigned to: arm 1, L-carnitine 4 g/day + Celecoxib 300 mg/day or arm 2, L-carnitine 4 g/day + celecoxib 300 mg/day + megestrol acetate 320 mg/day, all orally. All patients received as basic treatment polyphenols 300 mg/day, lipoic acid 300 mg/day, carbocysteine 2.7 g/day, Vitamin E, A, C. Treatment duration was 4 months. Planned sample size was 120 patients.
Results: According to the statistical design an interim analysis was planned for futility after the enrolment of 60 patients. The results did not show a significant difference between treatment arms: therefore, the trial was stopped for futility. Analysis of changes from baseline showed that LBM (by dual-energy X-ray absorptiometry and by L3 computed tomography) increased significantly in both arms. REE and fatigue decreased significantly in both arms. Among secondary endpoints, GPS and ECOG PS score decreased significantly in both arms. Physical performance assessed by 6MWT improved significantly in both arms. Toxicity was quite negligible and comparable between arms.
Conclusion: The results of the present study enable us to suggest a simple, feasible, effective and safe, low cost two-drug treatment for CACS including nutraceuticals (i.e., antioxidants): this combination has a favorable cost-benefit profile while achieving optimal patient compliance.

3074 POSTER

Efficacy of Manual Lymphatic Drainage and Intermittent Pneumatic Compression Pump in Treatment of Lypmhedema After Mastectomy

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Background: Lymphedema can cause many problems including pain, impaired extremity function, unsatisfactory cosmetics and psychological and social issues.
Objective: The aim of this study was to compare the efficacy of manual lymphatic drainage and intermittent pneumatic compression pump in the management of lypmhedema.
Materials and Methods: Thirty patients with upper extremity lymphedema following the mastectomy were randomized into two groups. In the first group (n = 15), the patients received allocated treatment including skin care, manual lymphatic drainage, compression bandage, compression garments and exercises. In the second group (n = 15), the patients had therapy including skin care, manual lymphatic drainage, intermittent pneumatic compression pump, compression bandage, compression garments and exercises. All groups were treated five times a week for three weeks (a total of 15 sessions).
The difference of circumference measurements of metacarphophalangeal joints, wrists, 10 cm below and above the lateral epicondyles, limb volume difference, dermal thickness and pain were assessed at the beginning, after the therapy (third week), and one month after completing the therapy (seventh week).
Results: The demographic variables such as age, body mass index (BMI), duration of lymphedema, number of lymph node dissection and type of surgery were similar between two groups ($p > 0.05$). We observed significant difference in both groups when we compared before and after the therapy with volumetric measurement method which was the gold standard for lymphedema. At the beginning median volume difference of group I was 630 (180–1820) and after the therapy it was 480 (0–1410). In group II, beginning median volume difference was 840 (220–3460) and after the therapy it was 500 (60–2160). However, no significant differences were observed between two groups in terms of the parameters mentioned above.
Conclusion: We concluded that manual lymphatic drainage and intermittent pneumatic compression pump are effective and safe treatments for reducing lymphedema. However, any superiority of pneumatic compression pump to manual lymphatic drainage could not be determined in this study.

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An Ultra Low Molecular Weight Heparin LMWH (Semuloparin) Blunts the Procoagulant Effect of Microparticles. the Rationale Behind Its Use in the Management of Thrombosis in Cancer Patients

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Background: Cancer patients are at high risk of thrombosis due to both endogenous pathogenesis and therapeutic interventions using radiation and chemotherapy. Microparticles (MP) with procoagulant effects along with other mediators are known to be upregulated in these patients. Low Molecular Weight Heparins (LMWH) have been used to manage cancer associate thrombosis. An ultra LMWH (semuloparin) with enriched Anti-Xa oligosaccharides has been shown to exhibit anti-tumour and anti-thrombotic effects in animal models.
Methods: To investigate the effect of semuloparin on the pro-coagulant actions on MPs on base line plasma samples collected from patients with inoperable small cell lung carcinoma (SCLC) (n = 100) and a heterogenous group of cancer patients who were recruited in the Oncenox study (n = 110). The control group comprised of plasma samples of 50 male and female healthy subjects. Microparticles were measured by a functional assay using an Annexin trapping and Thrombin generation was measured with an amidolytic assay (Hyphen labs, Paris, France).
Results: In comparison to the normal plasma samples (3.6 ± 0.7nm), the MPs in the SCLC (11.6 ± 3.1nm) and the Oncenox group (14.1 ± 2.8nm) showed markedly increased levels. Similarly in the Thrombin generation assays in comparison to the normals (460 ± 30nm) higher levels of thrombin were generated in the SCLC (530 ± 72) and Oncenox (610 ± 90nm) groups. Supplementation of semuloparin at an 1 μg/ml resulted in marked suppression of the functional MPs and Thrombin generation activities in all plasma samples in all groups. The suppression of the MP functionality was 36% for normals, 55% for SCLC and 60% for Oncenox. Similar results were obtained in the Thrombin generation assays. A direct correlation between MP and Thrombin generation activities was evident in all three groups.
Conclusion: This study underscores the importance of procoagulant mediators such as MPs in cancer. The decrease of MP functionality along with the inhibition of thrombin generation by semuloparin, strongly supports the rationale to use this agent in the management of malignancy associated thrombosis.

3076 POSTER

Fatigue Experienced by Patients During Cancer Treatment − the Psychometric Properties of the Swedish Version of the Revised Piper Fatigue Scale

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Background: The Revised Piper Fatigue scale is one of the most used instruments to specifically assessed cancer related fatigue. The objective of this study was to investigate the psychometric properties of the Revised Piper Fatigue scale for use in Swedish cancer patients.
Materials and Methods: In a cross sectional design 300 cancer patients undergoing curative radiotherapy completed the Swedish version of the Revised Piper Fatigue scale and the Multidimensional Fatigue Inventory-20 after 4−5 weeks of treatment.